



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration  
New Orleans District  
Southeast Region  
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New Orleans, Louisiana 70127

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July 1, 2003

**WARNING LETTER NO. 2003-NOL-17**

**FEDERAL EXPRESS**  
**OVERNIGHT DELIVERY**

Mrs. Trina T. Nguyen, Owner  
DIP Seafood Mudbugs  
1870 Dauphin Island Parkway  
Mobile, Alabama 36605

Dear Mrs. Nguyen:

We inspected your firm, located at 1870 Dauphin Island Parkway, Mobile, Alabama, on April 8, 9, 11 & 15, 2003. We found that you have serious deviations from the Fish and Fishery Products Hazard Analysis and Critical Control Point Regulation (Seafood HACCP regulation), Title 21, Code of Federal Regulations, Part 123 (21 C.F.R. 123). In accordance with 21 C.F.R. 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your cooked, ready-to-eat crawfish is adulterated, in that the crawfish has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulation through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

Your deviations are as follows:

- You must have a HACCP plan that lists the critical limits that must be met to comply with 21 C.F.R. 123.6 (c)(3). A critical limit is defined in 21 C.F.R., Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for cooked, ready-to-eat crawfish lists a critical limit of [REDACTED] at the cooling critical control point that is not adequate to control the food safety hazard of pathogen growth. The FDA's Fish And Fisheries Products Hazards And Controls Guidance, (The Guide) Third Edition (see <http://www.cfsan.fda.gov/~comm/haccpsea.html>), recommends the product be cooled to 70°F or below within 2 hours and to 40°F or below within another 4 hours.

- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 C.F.R. 123.6(b). However, your firm did not follow the temperature monitoring procedure of “recording thermometer” at the “cooler/refrigerated storage” critical control point to control pathogen growth as listed in your HACCP plan for cooked, ready-to-eat crawfish. The cooler temperature should be monitored on a continuous basis. This can be accomplished by installing a temperature-recording device to provide monitoring records of the cooler temperatures during non-business hours, holidays, and weekends.
- You must have a HACCP plan that, at a minimum, lists monitoring procedures and frequency for each critical control point to comply with 21 C.F.R. 123.6(c)(4). However, your firm’s HACCP plan for cooked crawfish lists a monitoring frequency at the cooking critical control point that is not adequate to control pathogen survival through cooking. Your firm’s HACCP plan lists a monitoring frequency of “each cooking” as the monitoring frequency at the cooking critical control point. The Guide recommends continuous monitoring of cooking temperatures at the cooking critical control point. The Guide further recommends the cooking temperature be monitored by a temperature recording device or a digital time/temperature data logger. The device should be installed in a manner that ensures the device accurately records the temperature of the coldest area of the cooking equipment.
- You must monitor sanitation conditions and practices adequately during processing to comply with 21 C.F.R. 123.11(b). However, your firm did not monitor the prevention of cross-contamination from insanitary objects to food and protection of food from adulteration with cleaning materials as evidenced by the following:
  - (1) Your food processing equipment was not maintained in a sanitary condition to prevent food from becoming adulterated. For example, a rusted chain routinely came into direct contact with cooked crawfish during cooking operations.
  - (2) You have not taken necessary precautions to protect raw ingredients from contamination. For example, paper bags of salt and loosely-lidded, plastic containers of [REDACTED] were stored in a manner such that water used in hand-washing and cleaning operations routinely soaked the paper bags and seeped into the plastic containers of the raw ingredients.

We may take further action if you do not correct these violations promptly. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as HACCP and sanitation monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

We recognize that at the close of the inspection you made a verbal commitment to correct the observed deficiencies; however, we note that this is the second Warning Letter that FDA has issued to your firm for deviations from the Seafood HACCP regulation. This letter may not list

all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation, and the Current Good Manufacturing Practice Regulation (21 C.F.R., Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your response to the attention of Cynthia R. Crocker, Compliance Officer, at 100 W. Capitol Street, Suite 340, Jackson, Mississippi 39269. If you have questions regarding the implementation of the Seafood HACCP regulation or the application of HACCP to your specific process, you may contact Ms. Crocker at (601) 965-4581 for answers, direction to guidance, and/or sources of training for achieving compliance.

Sincerely,

A handwritten signature in black ink, appearing to read "Carl E. Draper", with a long, sweeping horizontal line extending to the right.

Carl E. Draper  
District Director  
New Orleans District

Enclosure: Form FDA 483